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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/570,346

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EXAMINER

MACFARLANE, STACEY NEE

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

02/12/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/570,346 | <b>Applicant(s)</b><br>NAKAGAWARA ET AL. |  |
|                              | <b>Examiner</b><br>STACEY MACFARLANE | <b>Art Unit</b><br>1649                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-13 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 4-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2008 has been entered.

### ***Response to Amendment***

2. Claim 3 has been amended and claim 13 newly added as requested in the amendment filed on December 12, 2008. Following the amendment, claims 1 and 3-13 are pending in the instant application.

Claims 1 and 4-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on November 19, 2007.

Claims 3 and 13 are under examination in the instant office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on December 12, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. While applicant may act as his or her own lexicographer the claim term must be clearly set forth. Claim 3 is vague and indefinite for the following: in part (a) the recitation "to give cultured neurons" in the last line, and in part (f) the word "candidate" in reference to compound. The metes and bounds of these recitations cannot be ascertained.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 3 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for screening a compound which inhibits the interaction between AICD and p53, does not reasonably provide enablement for the identification of a drug for the treatment of Alzheimer's. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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10. The nature of the invention is a method for screening and identifying compounds that are useful for the treatment of Alzheimer's disease. While the specification provides enough guidance such that one of ordinary skill in the art would be able to perform the active steps required by the claims without undue experimentation, the specification does not provide enough guidance or direction such that a skilled artisan would be able to develop said compounds as effective drugs for the treatment of Alzheimer's disease with a reasonable expectation of success.

11. The court has stated: "[A] claim preamble has the import that the claim as a whole suggests for it."; *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim." (*Id.*).

12. In the instant case the result of the method recites "wherein ...is indicative of the compound inhibiting binding between AICD and p53". The specification provides no nexus between compounds that inhibit the binding between AICD and p53 and compounds that successfully treat Alzheimer's disease. Therefore the specification does not enable a skilled artisan to use the invention commensurate in scope with these claims.

13. While one of ordinary skill in the art would be able to perform the active steps required in order to practice the claimed method for screening, one would not know how to use those compounds for the treatment of Alzheimer's disease without undue

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experimentation. As the following reference indicates, even within the current state of the art much unpredictability remains within the art of drug development for the treatment Alzheimer's disease (Pritchard JF, BMC Neuroscience, 9 Suppl 3:S1, December 2008). Specifically, the Pritchard reference teaches that drug development has decreased despite the rapidly expanding base of therapeutic targets and screening via high-throughput methods, and in part, the decrease is due to the fact that current animal models of Alzheimer's disease have poor predictive validity for the treatment of humans. The reference describes in great detail the various hurdles within the process of drug development (page 2, ¶ 8 through end).

14. Given the lack of guidance with respect to a nexus between inhibition of binding between AICD and p53 and the pathology of Alzheimer's disease as well as the unpredictability within the art of drug development, one of ordinary skill in the art would have to make a further inventive contribution in order to use the method as claimed for the screening of a compound for the treatment of Alzheimer's disease. Therefore, the specification is not enabled commensurate in scope with the claims.

#### ***Allowable Subject Matter***

15. Claims 3 and 13 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, set forth in this Office action.

#### ***Conclusion***

16. No Claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-W and ALT F 5:30 to 3:30, TELEWORK-Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane  
Examiner  
Art Unit 1649

/Olga N. Chernyshev/  
Primary Examiner, Art Unit 1649